UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION	**MDL No. 15-2666 (JNE/FLN)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF DR. RICHARD P. WENZEL

I. PRELIMINARY STATEMENT

Defendant 3M's proffered expert witness on infectious disease, Dr. Richard P. Wenzel, expresses unreliable opinions related to general causation in this case, *i.e.*, whether the Bair Hugger forced air warming device is capable of causing periprosthetic joint infections in patients undergoing total knee replacement or total hip replacement surgery. Additionally, Dr. Wenzel provides testimony regarding two topics outside his area of qualifications, namely, hypothermia and laminar airflow. Because he is not qualified to opine about these topics, the Court should exclude or restrict Dr. Wenzel's opinions and testimony pursuant to Rule 702 of the Federal Rules of Evidence.

II. DR. WENZEL'S TESTIMONY AND OPINIONS SHOULD BE EXCLUDED AS THEY ARE UNRELIABLE AND IRRELEVANT

A. The Court Should Exclude Dr. Wenzel's Opinion that the Bair Hugger Does Not Cause Periprosthetic Joint Infections

Dr. Wenzel expresses the general causation opinion that there is insufficient evidence to conclude that the Bair Hugger device is generally capable of causing a periprosthetic joint infection. Ex. B (Wenzel Rpt. at 74.) The mere fact that Dr. Wenzel cannot testify one way or the other with respect to whether the Bair Hugger causes periprosethitic joint infections provides no assistance to the trier of fact.

While a literature review is an acceptable methodology, Dr. Wenzel's purported methodology of evaluating the literature is applied inconsistently. For instance, in spite of acknowledging Darouiche as an expert[1] and recognizing Darouiche's study as

[1] Ex. A (Wenzel Dep. at 78:14-18.)

authoritative, Dr. Wenzel criticized the Darouiche study[2] for not doing microbiological testing, and for having an insufficient sample size to determine a causal relationship.[3] The Darouiche study shows a correlation between bacterial load in the air and periprosthetic joint infections.[4] Importantly, the findings in Darouiche contradict Dr. Wenzel's opinion that infection-causing bacteria originate solely from the patient's own skin.[5]

Dr. Wenzel failed to levy the same criticisms against the studies on which he relied as he did against the Darouiche study and other studies that support the Plaintiffs' case, even though some of those studies had the very same purported limitations.[6] His selective "cherry-picking" of supportive articles while overlooking limitations and methodological flaws in those articles illustrates the biased nature of his supposedly scientific review process. Dr. Wenzel and 3M criticize the peer-reviewed article by McGovern and his esteemed co-authors while at the same time Dr. Wenzel relies on un-published internal work by Augustine and his associates--the so called "secret" studies.

While 3M accuses the researchers of keeping these results "secret," just the opposite is true. 3M has kept secret multiple internal CFD studies looking at these exact issues in the case. Dr. McGovern (who never worked for Augustine) testified at length that his only attempt to culture bacteria from the Bair Hugger was "not a good study" due to numerous methodological limitations. Dr. Legg (who was also never employed by

---

[2] Darouiche, et al. *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*, INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY (2017).
[3] Ex. A (Wenzel Dep. at 167; 352:6-7.)
[4] *Id.*
[5] *Id.*
[6] Ex. B (Wenzel Rpt. 6-37.)

Augustine) corroborated those issues, testifying about the inherent difficulties of using agar plates to capture bacteria in operating rooms. These informal tests should be viewed as what they were: nascent efforts to understand a newly-discovered and poorly-understood scientific issue that took time and further research to fully flesh out. 3M has thousands of studies and tests performed on the Bair Hugger that were never published, yet, Dr. Wenzel does not label those studies as "secret" or imply the failure to disclose and/or publish them is presumptively nefarious.

Dr. Wenzel admits that he extracted favorable data from reports, cited the data out of context, and used that non-contextual data to support his preformed opinion, even where that study explicitly contradicts Dr. Wenzel's primary opinion.[7] Dr. Wenzel opined that not even evidence of airborne contamination of the wound by particles generated by the Bair Hugger would alter this preconceived notion that the Bair Hugger device cannot contribute to infection in orthopedic device surgeries.[8] His own textbook, which blatantly contradicts his opinion, states "Airborne bacteria originating from the surgical team suffice to create [surgical site infections] in these types of procedures, particularly when implants are being placed (example, total hip prostheses)," For litigation purposes, Dr. Wenzel will not admit what he has previously opined in academia: that airborne bacteria can cause periprosthetic joint infections.[9] Again, Dr. Wenzel's litigation-driven bias should be seen as a modification of his opinion for purposes of supporting a client that has been the source of most of his recent income,

[7] Ex. A (Wenzel Dep. at 174-176.)
[8] *Id.* at 350:6-22.
[9] Ex. A (Wenzel Dep. at 362:5-365:15).

rendering his opinions highly suspect and potentially untrustworthy and not reliable under Rule 702.

B. Dr. Wenzel's Opinion that Skin Bacteria at the Surgical Site Cause Periprosthetic Joint Infections is Unreliable and Thus Should be Excluded

Dr. Wenzel opines that the mostly likely cause of the periprosthetic joint infections are bacteria on the patient's own skin.[10] Dr. Wenzel persists with his novel hypothesis that the infection-causing bacteria come only from a patient's skin at or near the surgery site even though he admits that a high proportion of the bacteria around the surgical site, and specifically on the patient's skin, are killed when the site is properly prepped.[11] In short, Dr. Wenzel recognizes that proper skin antisepsis, which can be determined from a careful review of medical records, is presumed to destroy all viable bacteria on a patient's skin, leaving none to serve as the source of a PJI. Under these circumstances, one must find an alternative explanation for bacteria to find their way to the deep joint space, but Dr. Wenzel is unable or unwilling to admit this alternative source may be explained by airborne contamination of the patient's wound by devices that blow contaminated air, like the Bair Hugger.

Instead, he clings to his incomplete and unsupported opinion but fails to provide any evidence to explain or support his hypothesis that residual skin-borne bacteria can make their way to the surgical wound even after proper skin antisepsis. Such is evidence since he simply has no explanation whatsoever as to the mode by which such bacteria

[10] Ex. A (Wenzel Dep. at 39:20-23.)
[11] Ex. A (Wenzel Dep. at 204:6.)

may be transmitted from the skin to the prosthetic device.[12] Specifically, Dr. Wenzel admits that he does not know how bacteria move from the skin and, under his hypothesis, get onto the prosthetic implant.[13] Dr. Wenzel just agrees that it somehow happens, although he provides no scientific evidence or methodology used to support this opinion.[14] This unsupported hypothesis lacks any discernible scientific methodology or foundation and is, therefore, unreliable. In the absence of some credible rationale or explanation as to how bacteria might reach the wound—other than airborne propagation—Dr. Wenzel's unsupported "belief" that the microbes fall, jump, or otherwise find their way to the implant should not be permitted to confuse the jury in this case.

Each step of a methodology used in reaching an opinion must be reliable for the opinion to be reliable. *See* Fed.R.Evid. 702. The lack of evidence for Dr. Wenzel's opinion is fatal. *See Glastetter v. Novartis*, 107 F. Supp. 2d 1015, 1045 (E.D. Mo. 2000). Dr. Wenzel's proffered opinion "is connected to the existing data only by the *ipse dixit*" of Dr. Wenzel. *General Elec. Co. v. Joiner*, 522 U.S. 136, 157 (1997). This is a prime instance where "[t]here is simply too great an analytical gap between the data and the opinion proffered." *Id.* at 136. Accordingly, the Court should exclude these opinions, and preclude Dr. Wenzel from offering any such unreliable testimony.

[12] *Id.* at 215:19- 216:11.
[13] *Id.*
[14] *Id.*

C. The Court Should Preclude Dr. Wenzel From Offering his Opinion About Patient Comorbidity and Infection Because It Is Irrelevant and Will Confuse the Jury

Dr. Wenzel's discussion of patient comorbidity[15] is irrelevant to the issue of general causation in this case. Dr. Wenzel admits that ***bacteria*** cause infection, ***not*** a patient's co-morbidities. Dr. Wenzel agreed many times that bacteria are necessary for infections, and that no comorbidity factor alone can ***cause*** infection[16] Dr. Wenzel's discussion of comorbidity speaks only to a patient's vulnerability or susceptibility to infection, not to the cause of the infection itself.

This Court must determine not only if the testimony is reliable, but also whether it has a valid connection to the pertinent inquiry. *Kumho Tire Co.*, 526 U.S. 137 at 149. Expert testimony must therefore "logically advance[] a material aspect of the proposing party's case." *Daubert*, 509 U.S. at 597. Dr. Wenzel's discussion of comorbidity is not relevant to this stage of the case -- general causation. Expert testimony also must be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir.) (*citing Daubert's* "fit" requirement), *cert. denied*, 531 U.S. 979 (2000). General causation is not about comorbidity or susceptibility to infection. "[A] tortfeasor takes his victim as he finds him." *Schaub v. VonWald*, 638 F.3d 905, 937 (8th Cir. 2011). Any discussion of a plaintiff's comorbidity therefore would not assist the trier of fact in determining the issue

[15] Ex. B (Wenzel Rpt. at 47-56); Ex. A (Wenzel Dep. at 271-279.)
[16] *Id.* at 275:13-15, 276:4-7, 276:21-277:4; 277:15-23, 278:2-12.

of general causation. Dr. Wenzel's opinions regarding comorbidity are irrelevant and will only confuse the trier of fact. *Kinergy*, No. 4:01CV00211 ERW, 2003 U.S. Dist. LEXIS 28291, at *42 (expert witness testimony excluded when opinions "are irrelevant to the action and will only confuse the trier of fact.")

In addition, Dr. Wenzel recently issued a supplemental report based solely on a recent non-science based letter sent by the FDA to "health care providers," purporting to recommend continued use of warming devices "when clinically warranted."[17] Both the supplemental report by Dr. Wenzel and the "letter" it relies on should be stricken and not considered by this Court as untimely, irrelevant, and beyond the scope of allowable evidence in this case.[18] Plaintiffs' have precious little information about this recent FDA letter, which was issued after the close of general causation discovery, giving Plaintiffs no opportunity to depose Dr. Wenzel or to conduct any other discovery into its basis and origin, and whether 3M or other device manufacturers influenced the timing and/or the substance of the letter.[19] Moreover, the FDA letter did not help form the basis of Dr. Wenzel's opinion concerning general causation, as it was not written until after his report

[17] *See* DX1, Supplemental Report of Dr. Richard P. Wenzel and the FDA's August 30, 2017 letter, attached to Defendant's Response Memo.

[18] *See, e.g., In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1833173, at *13 (N.D. Ill. May 8, 2007) ("[A]lthough the FDA may have a different interpretation of the studies relied upon by plaintiffs' experts' it is left to the trier of fact, not the reviewing court, to decide how to weigh the competing expert testimony."); I*n re Celexa & Lexapro Liab. Litig.*, 927 F. Supp. 2d at 765 (refusing to exclude expert testimony despite contrary finding and statements from the FDA).

[19] In fact, Plaintiffs' propounded additional RFP's on this issue, but 3M refused to produce any responsive documents, claiming that they were not required to do so given the close of general cause discovery and other grounds. Further, they stated that any non-privileged documents they have will not be produced until after October 30, 2017, once the *Daubert* hearings in this matter have concluded.

and deposition were completed. Regardless, however, the letter has little if any probative value, as it is not a peer reviewed scientific publication, and would unfairly prejudice the Plaintiffs if the imprimatur of the federal government is allowed to influence the jury without any ability of Plaintiffs to obtain information about its connection to manufacturers.

III. CONCLUSION

Defendant 3M cannot meet its burden to admit Dr. Wenzel's opinions. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007) (explaining that the party seeking admission of expert testimony has the burden of demonstrating its reliability). Dr. Wenzel's general causation opinions are unreliable and irrelevant for the reasons stated above.

Accordingly, the Court should **GRANT** Plaintiffs' motion and exclude Dr. Wenzel's opinion testimony.

Respectfully submitted,

Dated: October 17, 2017

CIRESI CONLIN L.L.P.

/s/Michael V. Ciresi_____
Michael V. Ciresi (MN #0016949)
Jan M. Conlin (MN #0192697)
Michael Sacchet (MN # 395817)
Ciresi Conlin LLP
225 S. 6th St., Suite 4600
Minneapolis, MN 55402
Phone: 612.361.8202
Email: MVC@CiresiConlin.com
JMC@CiresiConlin.com
MAS@ciresiconlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman
Genevieve M. Zimmerman (MN #330292)
1616 Park Avenue South
Minneapolis, MN 55404
Phone: (612) 339-9121
Fax: (612) 339-9188
Email: gzimmerman@meshbesher.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.
Ben W. Gordon (FL # 882836) – *Pro Hac Vice*
J. Michael Papantonio (FL # 335924)
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
Phone: (850) 435-7090
Fax: (850) 436-6090
Email: bgordon@levinlaw.com

Plaintiffs Co-Lead Counsel